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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/699,189 | 10/31/2003 | Robert G. Aslanian | AL01348K18 | 3527 |
| 24265 | 7590 | 08/24/2006 | EXAMINER | |
| SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530 | | | CHANG, CELIA C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,189

Applicant(s)

ASLANIAN ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-25, 44-46 and 51-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-25, 44-46, 51-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17:2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A preliminary amendment was filed canceling claims 1, 26-43, 47-50. Claims 2-25, 44-46, 51-61 are pending.

2. ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 58-61, drawn to method and composition of treating allergy using combination of compound 287 and loratadine or desloratadine, classified in class 514, subclass 256+. Claims 2-25, 56, 57 can be prosecuted with the group to the extend of the elected compound and loratadine or desloratadine.
- II. Claims 46, 51, 52, 55, drawn to method and composition of treating allergy using combination of compounds except 287 and loratadine or desloratadine, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a species of compound of claim 51 is also required. Claims 2-25, 56, 57 can be prosecuted with the group to the extend of the elected compound and loratadine or desloratadine.
- III. Claims 45, 51, 52, 54, drawn to method and composition of treating allergy using combination of compound and fexofenadine or cetirizine, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single species of compound of claim 51 and an election of fexofenadine or ceterizine is also required. Claims 2-25, 56, 57 can be prosecuted with the group to the extend of the elected compound and the elected fexofenadine or ceterizine.
- IV. Claims 44, 51, 52, 53, drawn to method and composition of treating allergy using combination of compound and an H1 receptor antagonist, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single species of compound of claim 51 and a H1 antagonist among those of claim 44 is also required. Claims 2-25, 56, 57 can be prosecuted with the group to the extend of the elected compound and the elected single H1 antagonist.

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- V. Claims 2-25, 56, 57, remaining compounds and ingredients drawn to method and composition for treating allergy using combination of compounds and H1 receptor antagonist, classified in class various, subclass various, depending on species election. If this group is elected a further election of a single disclosed compound not encompassed by claim 51 and a single disclosed H1 antagonist not encompassed by claims 44 is also required. Further restriction may be required.

The inventions are independent or distinct, each from the other because:

The search for each combination is not co-extensive of each other but depending on the particular species being elected. A classification cannot be determined without election of a compound and one other H1 antagonist. The merit determination for a combination method and composition based on the nature of the ingredients, the quantitative relationship and sequence of administration. For example, a search for combination containing Loratadine or desloratadine is in class 514 subclass 290, combination containing fexofenadine is in class 514 subclass 320, combination containing cetirizine is in class 514 subclass 250, combination containing astemizole is in class 514 subclass 322. Absent of an election of the particular active ingredient, no generic search can be performed, thus, the searches are not co-extensive of each other. The search for each particular combination not only required electronic search of all the literature and is very burdensome when enormous number of subclasses are involved.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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In the instant case, then there could have been no patentability of all the claims since similar compounds have been used in combination with all the H1 antagonists see WO 00/21512.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 10, 2006


Celia Chang
Primary Examiner
Art Unit 1625